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(54) Title: CONDOM

(57) Abstract: A condom has a vasodilator active compound applied to its external surface, preferably disposed towards the open end of the condom whereby, in use during intercourse, the compound makes contact with the vaginal meatus or proximal region of the vagina, such that the vasodilator is absorbed through the lining of the vagina to stimulate and increase the flow of blood in the labia and through the clitoris to promote engorgement thereof to alleviate symptoms associated with female inorgasmia.

Condom

This invention relates to condoms and is particularly intended to provide a condom for provision of sexual stimulation to the female partner of the user, in order to alleviate female sexual dysfunction, to enhance sexual pleasure and to improve condom safety through lowering condom failure due to rupture, by increasing vaginal secretion and lubrication.

It is recognised that female sexual dysfunction is a complex condition which, due to its various causes, cannot readily be treated by use of a particular drug or device. Nevertheless, an increase in vaginal blood flow and clitoral engorgement is known to be associated with increased vaginal secretions, a decrease in dyspareunia and increases in clitoral sensation, orgasmic response and sexual desire. It is an object of the present invention, therefore, to provide a means of stimulating the female genitalia during intercourse to increase vaginal blood flow.

In one aspect, the invention provides a condom having applied to its external surface a vasodilator active compound.

The vasodilator active compound is preferably disposed and retained in a localised region towards the open end of the condom whereby, in use during intercourse, the compound makes contact with the vaginal meatus or proximal region of the vagina, such that the vasodilator is absorbed through the lining of the vagina to stimulate and increase the flow of blood in the labia and through the clitoris to promote engorgement thereof which, itself, will lead to further or enhanced stimulation and result in increased vaginal secretions. Symptoms associated with female inorgasmia will thus be alleviated.

By use of the invention, a further advantage is that increased vaginal secretions result in increased lubrication between the wall of the vagina and the condom resulting in a lower rate of condom failure due to rupture.

In condoms according to the present invention, the active compound may be contained or impregnated in or coated on the external surface of the condom. The vasodilator may be applied as a composition which includes a carrier material with which the vasodilator compound is miscible but which will release the vasodilator active compound when in contact with body tissue. Where the condom is coated with a lubricant, the vasodilator active compound may be dispersed or dissolved in the lubricant but preferably is disposed on the condom surface in a form or within a composition which is immiscible with the

lubricant, whereby the compound is localised substantially at the zone of application to the condom surface. The active compound on such condoms, when they are in their rolled-up state for packaging purposes, thus tends to resist translocation from the external surface to adjacent portions of the internal surface, whereby the active compound is retained predominantly on the external surface and within the original zone of application. Preferably, the lubricant is buffered to an acidic pH, for example between 3 to 5, to prevent hydrolysis of the vasodilator active compound.

Condoms according to the present invention may include a textured or undulating region to the external surface, to provide enhanced physical stimulation to the female genitalia during intercourse to increase sexual sensation. The textured or undulating region may be located towards the open end of the condom so that the proximal parts of the vagina and the clitoris are preferentially stimulated by contact with the texturing or undulations. The textured or undulating region preferably incorporates or includes the vasodilator active compound. The texturing or undulations may comprise ribs or an array of individual protrusions or may comprise merely a roughened surface region, formed either by imparting a pattern to the surface of the condom or by application to the surface thereof of a particulate material or a material having a high coefficient of surface friction, such as a highly plasticised elastomer. The textured surface may be formed by manufacturing the condom on a mandrel or mould having an appropriate pattern of ribs, dots or other texturing etched into or embossed on its surface or by applying to the condom a material which results in a textured surface, for example by extruding a thin stream of the material from a nozzle so as to form a series of rings around the condom or by spraying the material in such a way that the surface becomes textured. A suitably textured extruded section can be applied direct to the condom at the time of its manufacture or subsequently, either by direct bonding or by the use of a pressure-sensitive, hot-melt or other suitable type of adhesive. Alternatively, a coating of a material can be applied for example by spraying, the coating then having a texturing applied to it by contact with a suitably patterned die so as to mould the surface in the desired textured shape.

The textured surface may be formed from one or more layers of material including the material from which the condom itself is formed. The material of at least one such layer should be miscible with the vasodilator and should allow the vasodilator to be absorbed by skin or tissue when brought in contact with the condom. Preferably, the material from which the condom is formed, either natural rubber latex or a synthetic rubber-like material, and any lubricant used therein, is immiscible with the vasodilator or the vasodilator-containing composition, whereby the vasodilator is restrained from migrating to other parts of the condom other than the zone of application. The material from which

the vasodilator-containing layer is formed will depend on the nature of the vasodilator active compound but, for active compounds such as organic nitrates, for example glyceryl trinitrate, suitable materials would include polar elastomers applied to the condom from solution, in the form of an aqueous dispersion of latex or by a hot melt or reactive process. Alternatively, the vasodilator-containing layer can be pre-formed and bonded subsequently to the condom using a suitable adhesive system as necessary.

The vasodilator active compound may comprise any known erectogenic compound which, on absorption through the skin or mucosa, locally enhances blood flow. Such compounds may include nitrates, long and short acting alpha-adrenoceptor blockers, ergot alkaloids, anti-hypertensives and the prostaglandins. Phosphodiesterase inhibitors, particularly type III and IV and most particularly type V can also be used, either alone or in combination with other vasodilators. Such compounds can be used alone or in combination and, optionally, together with skin penetration enhancers such as azone, dimethylsulfoxide, dimethyl formamide, N,N-dimethylacetamide, decylmethylsulfoxide, polyethylene glycol monolaurate, glycerol monolaurate, lecithin and 1-substituted azacycloheptan-2-one.

Useful nitrates and similarly acting compounds include nitro-glycerine, isosorbide dinitrate, erythrityl tetranitrate, amyl nitrate, sodium nitroprusside, molsidomine, linsidomine chlorydrate ("SIN-1"), S-nitroso-N-acetyl-d,1-penicillamine ("SNAP"), S-nitroso-N-cysteine, S-nitroso-N-glutathione ("SNO-GLU") and diazenium diolates ("NONOates"). A particularly useful nitrate is nitro-glycerine.

Natural prostaglandins that can be used include PGE₀, PGE₁, PGA₁, PGB₁, PGF₁alpha, 19-hydroxy-PGA₁, 19-hydroxy-PGB₁, PGE2, PGA₂, PGB₂, 19-hydroxy-PGA₂, 19-hydroxy-PGB₂, PGE₃, PGF₃alpha. Semi synthetic and synthetic prostaglandins such as carboprost tromethamine, dinoprost tromethamine, dinoprostone, lipoprost, gemeprost, metenoprost, sulprostane and tiaprost can also be used. A particularly useful prostaglandin is prostaglandin E₁ (PGE₁) or its synthetic version, alprostadil. Esters of the prostaglandins, such as the methyl and ethyl esters, can also be used.

Suitable alpha-adrenoceptor blockers include phenoxybenzamine, dibenarnine, doxazosin, terazosin, phentolamine, tolazoline, prazosin, trimazosin, alfuzosin, tamsulosin and indoramin.

Ergot alkaloids include ergotamine and ergotamine analogs, e.g., acetergamine, brazergoline, bromerguride, cianergoline, delorgotriole, disulergine, ergonovine maleate,

ergotamine tartrate, etisulergine, lergotrile, lysergide, mesulergine, metergoline, metergotamine, nicergoline, pergolide, propisergide, proterguride and terguride. A particularly effective alkaloid is yohimbine hydrochloride.

Non-specific phosphodiesterase inhibitors that can be incorporated into the condom include theophylline, IBMX, pentoxyphylline and papaverine, and direct vasodilators such as hydralazine. Papaverine is particularly useful either alone or in combination with phentolamine.

Examples of type III phosphodiesterase inhibitors that may be used include bipyridines such as milrinone and amirinone, imidazolones such as piroximone and enoximone, dihydropyridazinones such as imazodan, 5-methyl-imazodan, indolidan and ICI1118233, quinolinone compounds such as cilostamide, cilostazol and vesnarinone, and other molecules such as bemoradan, anergrelide, siguazodan, trequinsin, pimobendan, SKF-94120, SKF-95654, lixazinone and isomazole.

Examples of suitable type IV phosphodiesterase inhibitors include rolipram and rolipram derivatives such as RO20-1724, nitraquazone and nitraquazone derivatives such as CP-77059 and RS-25344-00, xanthine derivatives such as denbufylline and ICI63197, and other compounds such as EMD54622, LAS-31025 and etazolate.

Examples of type V phosphodiesterase inhibitors include zaprinast, MY5445, dipyridamole, vardenafil, and sildenafil. Other suitable type V phosphodiesterase inhibitors are disclosed in PCT Publication Nos. WO 94/28902 and WO 96/16644. A particularly useful type V phosphodiesterase inhibitor is sildenafil. Still other type V phosphodiesterase inhibitors useful in conjunction with the present invention include: IC-351 (ICOS); 4-bromo-5-(pyridylmethylamino)-6-[3-(4-chlorophenyl)propoxy]-3(2H)pyridazinone; 1-[4-[(1,3-benzodioxol-5-ylmethyl)amino]-6-chloro-2-quinazolinyl]-4-piperidine-carboxylic acid, monosodium salt; (+)-cis-5,6a,7,9,9a-hexahydro-2-[4-(trifluoromethyl)-phenylmethyl-5-methyl-cyclopent-4,5]imidazo[2,1-b]purin-4(3H)one, furazlocillin; cis-2-hexyl-5-methyl-3,4,5,6a,7,8,9,9a-octahydrocyclopent[4,5]imidazo[2,1-b]purin-4-one; 3-acetyl-1-(2-chlorobenzyl)-2-propylindole-6-carboxylate; 4-bromo-5-(3-pyridylmethylamino)-6-(3-(4-chlorophenyl) propoxy)-3-(2H)pyridazinone; 1-methyl-5-(5-morpholinoacetyl-2-n-propoxyphenyl)-3-n-propyl-1,6,-dihydro-7H-pyrazolo(4,3-d)pyrimidin-7-one; 1-[4-[1,3-benzodioxol-5-ylmethyl)amino]-6-chloro-2-

quinazolinyl]-4-piperidinecarboxylic acid, monosodium salt; Pharmaprojects No. 4516 (Glaxo Wellcome); Pharmaprojects No. 5051 (Bayer); Pharmaprojects No. 5064 (Kyowa Hakko; see WO 96/26940); Pharmaprojects No. 5069 (Scherin Plough); GF-196960 (Glaxo Wellcome); and Sch-51866.

Other compounds that can be used include nimodipine, pinacidil, cyclandelate, isoxsuprine, chloromazine, haloperidol, Rec15/2739 and trazodone, as well as anti-hypertensive agents including diazoxide, hydralazine and minoxidil.

The active compound or compounds optionally together with skin penetration enhancers may be applied direct to the appropriate region of the condom or as a composition dispersed or dissolved in a suitable carrier media, for example a gel carrier comprising a liquid medium and a thickening agent. According to another aspect of the invention, therefore, a composition for application to the external surface of a condom after unrolling on an erect penis comprises a vasodilator active compound and a carrier material.

In yet another embodiment, the invention provides a method of treating female sexual dysfunction, the method comprising the use during sexual intercourse of a condom having applied to the external surface a vasodilator active compound.

A condom according to the invention may also have a vasodilator active compound applied to the interior surface, in order to assist in maintaining an erection of the penis and, thus, providing for additional condom safety in prevention of premature and involuntary unsheathing of the condom from an otherwise partially-erect or flaccid penis. A compound applied to the interior surface may be localised at or towards the head end and may be the same or a different active compound to that applied to the external surface.

Embodiments of the invention will now be described by way of example only.

Example 1

A condom having a textured portion towards the open end was made by dipping a former into compounded natural rubber latex, the former having a series of grooves etched into its surface so as to form a series of ribs near the open end of the condom. After the condom was removed from the former it was mounted on a mandrel and a thin coating of a plasticised thermoplastic elastomer (a tri-block copolymer of styrene and butadiene) dissolved in a suitable solvent containing glycerol trinitrate absorbed onto lactose was

applied by roller to the ribbed portion of the condom. The solvent was evaporated to leave the coating on the textured portion. The condoms were then rolled off the mandrel and lubricated and packed as normal. A water-based lubricant, which is immiscible with glycerol trinitrate, was selected. The presence of the lactose enhanced the texture of the ribs and acted as a source of glycerol trinitrate.

Example 2

A 10 mm wide strip of a plasticised thermoplastic elastomer containing glycerol trinitrate dissolved in monopropylene glycol was extruded onto release paper using a die to form a profile having a number of raised ribs. The extruded strip, still on the release paper, was cut into a number of strips, the length of each strip being the circumference of the condom. Standard, parallel sided, non-ribbed condoms were mounted onto suitable mandrels and the strips were wrapped around the condoms near to the open end. The strips were then made to adhere to the condom by applying a heated roller and the release paper was removed. The condoms were then rolled, lubricated and packed as normal.

Example 3

A standard, un-ribbed condom was mounted on a mandrel and a thin film of a plasticised thermoplastic elastomer dissolved in a suitable solvent was sprayed onto the condom in a narrow band close to its open end. The elastomer contained glycerol trinitrate dissolved in monopropylene glycol. The solvent was removed by evaporation and the mandrel was brought into contact with a hot embossed roller so that the roller pressed onto the band. The mandrel was rotated so as to leave an embossed pattern in the band. The condom was removed from the mandrel and then lubricated and packed.

Claims

1. A condom having applied to its external surface a vasodilator active compound.
2. A condom according to claim 1, in which the vasodilator active compound is disposed towards the open end of the condom.
3. A condom according to claim 1 or claim 2, in which the active compound is applied as a coating to the external surface of the condom.
4. A condom according to claim 3, in which the active compound is applied as a composition which includes a carrier material with which the vasodilator compound is miscible but which will release the vasodilator active compound when in contact with body tissue.
5. A condom according to any preceding claim and coated with a lubricant, the vasodilator active compound being disposed on the condom surface in a form or within a composition which is immiscible with the lubricant.
6. A condom according to claim 5, including the lubricant is buffered to a pH between 3 and 5.
7. A condom according to any preceding claim, in which a textured or undulating region to the external surface.
8. A condom according to claim 7, in which the textured or undulating region extends at least towards the open end of the condom and incorporates or includes the vasodilator active compound.
9. A condom according to claim 8, in which the textured or undulating region is formed from one or more layers of material including the material from which the condom itself is formed, the material of at least one such layer being miscible with the vasodilator and allowing the vasodilator to be absorbed by skin or tissue when brought in contact with the condom.
10. A condom according to any preceding claim, in which the vasodilator active compound is selected from nitrates, long and short acting alpha-adrenoceptor blockers, ergot alkaloids, anti-hypertensives, the prostaglandins and phosphodiesterase inhibitors optionally in combination with a skin penetration enhancer.
11. A condom according to claim 10, in which the vasodilator active compound comprises an organic nitrate applied as a layer or coating in a polar elastomer in solution, in the form of an aqueous dispersion of latex or by a hot melt or reactive process.

12. A condom according to any preceding claim, in which the active compound optionally together with a skin penetration enhancer is applied to the condom as a composition dispersed or dissolved in a gel carrier comprising a liquid medium and a thickening agent.
13. A composition suitable for application to the external surface of a condom after unrolling on an erect penis, the composition comprising a vasodilator active compound and a gel carrier material.
14. A method of treating female sexual dysfunction, the method comprising the use during sexual intercourse of a condom having applied to the external surface a vasodilator active compound.
15. A condom according to any of claims 1 to 12, further including a vasodilator active compound applied to the internal surface of the condom.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(75) Inventor/Applicant (*for US only*): **BARDER, James, Henry [GB/GB]**; Naylands, Slaugham, West Sussex RH17 6AG (GB).

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(54) Title: CONDOM

(57) Abstract: A condom has a vasodilator active compound applied to its external surface, preferably disposed towards the open end of the condom whereby, in use during intercourse, the compound makes contact with the vaginal meatus or proximal region of the vagina, such that the vasodilator is absorbed through the lining of the vagina to stimulate and increase the flow of blood in the labia and through the clitoris to promote engorgement thereof to alleviate symptoms associated with female inorgasmia.

INTERNATIONAL SEARCH REPORT

Application No PCT/GB 03/01586

A. CLASSIFICATION OF SUBJECT MATTER			
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			A61P15/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61K A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
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EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02 00240 A (QUALILIFE PHARMACEUTICALS INC) 3 January 2002 (2002-01-03) page 1 page 5 -page 7, line 27 claims	1-4, 10-13
P, X	WO 02 39945 A (ICEBELLA ENTERPRISE LTD) 23 May 2002 (2002-05-23) page 2, paragraph 2 -page 4, paragraph 3 claims; figures	1,7-13
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A	US 4 829 991 A (BOECK ROBERT F) 16 May 1989 (1989-05-16) claims; figures	1-13,15
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the International filing date but later than the priority date claimed

- "T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

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Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

Application No

PCT/GB 03/01586

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 333 621 A (DENZER ERIC) 2 August 1994 (1994-08-02) claims; figures ---	1-13,15
A	WO 99 21562 A (VIVUS INC) 6 May 1999 (1999-05-06) the whole document ---	1-13,15
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A	WO 99 56666 A (RT ALAMO VENTURES INC) 11 November 1999 (1999-11-11) claims ---	1

INTERNATIONAL SEARCH REPORTapplication No.
PCT/GB 03/01586**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 14 because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT – Method for treatment of the human or animal body by therapy
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Application No PCT/GB 03/01586	
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INTERNATIONAL SEARCH REPORT

Application No
PCT/GB 03/01586

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PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 09 NOV 2004
INTERNATIONAL PRELIMINARY EXAMINATION REPORT PCT

Applicant's or agent's file reference ISH/P104001	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA416)	
International application No. PCT/GB 03/01586	International filing date (day/month/year) 14.04.2003	Priority date (day/month/year) 16.04.2002
International Patent Classification (IPC) or both national classification and IPC A61F6/04		
Applicant FUTURA MEDICAL DEVELOPMENTS LIMITED		

<ol style="list-style-type: none"> 1. This International preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. 2. This REPORT consists of a total of 5 sheets, including this cover sheet. <ul style="list-style-type: none"> <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). <p>These annexes consist of a total of 1 sheets.</p>
<ol style="list-style-type: none"> 3. This report contains indications relating to the following items: <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the International application

Date of submission of the demand 12.11.2003	Date of completion of this report 03.11.2004
Name and mailing address of the International preliminary examining authority:  European Patent Office - Gitschner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Kuehne, H-C Telephone No. +49 30 25901-579



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB 03/01586

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-6 as originally filed

Claims, Numbers

1-10 received on 13.10.2004 with letter of 13.10.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

5. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB 03/01586

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims	1-10
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-10
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-10
	No:	Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/01586

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: WO 02/00240 A (QUALILIFE PHARMACEUT INC) 3 January 2002 (2002-01-03)

D1 which is considered to represent the most relevant state of the art discloses (see page 7, lines 24-27) compositions and methods for treating females sexual response by administering to the vagina a vasodilator composition in combination with lubricant as a wet film or coating on the exterior surface of a male condom.

The subject-matter of claim 1 differs from this known D1 in that the vasodilator compound is disposed on the external condom surface in a form or within a composition which is immiscible with the lubricant.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as the translocation of the vasodilator active compound from the external surface of the condom when it is in its rolled-up state for packaging purposes (page 2, paragraph 1 of the application).

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

This solution is not obvious. None of the documents cited in the search reports hints to such a solution. Even though D1 discloses libraries of vasodilator active compounds (page 1, line 21 -page 6, line 23), of "pharmaceutically acceptable carrier" (also used as lubricants; page 8, line 14 - page 9, line 25) and pharmaceutical forms (page 6, lines 30 and 31) this document do not hint to a solution of claim 1, since the synergistic effect of using a combination of a vasodilator active compound which is immiscible with the lubricant is neither explicitly nor implicitly disclosed in D1.

Claims 2-10 are dependent on claim 1 and as such also meet the requirements of the PCT

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB 03/01586

with respect to novelty, inventive step and industrial applicability.

Claims

1. A condom having applied to its external surface a vasodilator active compound and being coated with a lubricant, characterised in that the vasodilator active compound is disposed on the external condom surface in a form or within a composition which is immiscible with the lubricant.
2. A condom according to claim 1, in which the vasodilator active compound is disposed towards the open end of the condom.
3. A condom according to claim 1 or claim 2, in which the active compound is applied as a composition which includes a carrier material with which the vasodilator compound is miscible but which will release the vasodilator active compound when in contact with body tissue.
4. A condom according to any preceding claim, in which the lubricant is buffered to a pH between 3 and 5.
5. A condom according to any preceding claim, in which the condom includes a textured or undulating region to the external surface.
6. A condom according to claim 5, in which the textured or undulating region extends at least towards the open end of the condom and incorporates or includes the vasodilator active compound.
7. A condom according to claim 6, in which the textured or undulating region is formed from one or more layers of material including the material from which the condom itself is formed, the material of at least one such layer being miscible with the vasodilator and allowing the vasodilator to be absorbed by skin or tissue when brought in contact with the condom.
8. A condom according to any preceding claim, in which the vasodilator active compound is selected from nitrates, long and short acting alpha-adrenoceptor blockers, ergot alkaloids, anti-hypertensives, the prostaglandins and phosphodiesterase inhibitors optionally in combination with a skin penetration enhancer.
9. A condom according to claim 8, in which the vasodilator active compound comprises an organic nitrate applied as a layer or coating in a polar elastomer in solution, in the form of an aqueous dispersion of latex or by a hot melt or reactive process.
10. A condom according to any preceding claim, in which the active compound optionally together with a skin penetration enhancer is applied to the condom as a composition dispersed or dissolved in a gel carrier comprising a liquid medium and a thickening agent.